April 21, 2020

Globalcare Medical Technology Co., Ltd
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153
ITALY

Re: K192609
Trade/Device Name: Globalcare GUS622 Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 4, 2020
Received: March 9, 2020

Dear Roger Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192609

Device Name
Globalcare GUS622 Blood Pressure Monitor

Indications for Use *(Describe)*

The Globalcare GUS622 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Name:	GUS622 Blood Pressure Monitor
Type of 510(k) submission:	Traditional
Date of submission:	4 March 2020
Manufacturer:	Globalcare Medical Technology Co., Ltd No.7 Factory, European Industrial Park No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City Guangdong, CHINA 528415
Phone:	+86-760-22589901
FDA Establishment Reg. Number:	3010880718
510(k) Owner and Submitter:	Globalcare Medical Technology Co., Ltd No.7 Factory, European Industrial Park No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City Guangdong, CHINA 528415
Owner/Operator Reg. Number:	10046812
510(k) Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	DXN
FDA Regulation Number:	21 CFR 870.1130
FDA Classification Name:	Noninvasive blood pressure measurement system
Classification Panel:	Cardiovascular
Common Name:	Upper arm blood pressure monitor
FDA Classification:	Class II
Submission Type:	510(k)
Indications for Use:	The Globalcare GUS622 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.

Device Description:
The Globalcare GUS622 Blood Pressure Monitor is an automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate.

The device is powered by batteries or by a mains-connected power supply.

The Globalcare GUS622 Blood Pressure Monitor comprises the following parts:

- Blood pressure monitor main device x1
- Upper arm cuff x1
- 1.5 V LR03 AAA batteries x4
- Storage bag x1
- Instructions for use x1
- 100-240Vac 50/60Hz power supply (optional) x1

None of the parts included with the device are supplied in a sterile condition.

The Globalcare GUS622 Blood Pressure Monitor main unit is an electronic unit incorporating a screen that displays results and other information relevant to device operation. The device is powered by batteries or by a mains-connected power adapter, and is designed for home ('OTC') use.

The clinical outputs from the GUS622 Blood Pressure Monitor are:

- Systolic pressure (mm Hg)
- Diastolic pressure (mm Hg)
- Pulse rate (1/min)
- Cardiac arrhythmia (Irregular heart beat (IHB)) symbol
- Level of risk
- Hemodynamic Rest Condition (HSD) indication

The device operates on the oscillometric method**:** pressure sensors on the cuff are used to capture pulse waves during constricted blood flow and the device then computes the results for display by means of an algorithm which analyses the pressures transmitted during arterial oscillations that occur during cuff deflation. See Section 16 of this submission for further details of the software utilized in the device.

Irregular heart beat (IHB) is detected by measuring the interval time between each heart beat and comparing these values with the average heart beat interval (heart beat per minutes shown on the display). If the difference between any heart beat interval and the average is higher or lower than 25 %, the device shows the cardiac arrhythmia (IHB) symbol on the display.

The pulse rate is determined by calculating the frequency of the oscillations in the cuff, which are cardiac synchronous.

The GUS622 is controlled by software which calculates the blood pressure (diastolic and systolic) and pulse rate by the oscillometric method. To do this, it also controls the pneumatic components to inflate the cuff (with a pump), holds the cuff pressure, and then deflates the cuff (by means of a solenoid valve). The software collects the relevant data from the pressure sensor during deflation.

The software also drives the LCD display, from which the user can read the result of the blood pressure and pulse rate measurements, and undertakes the Hemodynamic Rest Condition (HSD) detection calculations, and reports whether any irregular heart beat is occurring.

Performance data:
The GUS622 has been tested and found to be in compliance with the following standards:

Safety and EMC:
- ANSI/AAMI ES60601-1:2005 / A2:2010

- IEC 60601-1-11:2015
- IEC 60601-1-2:2014
- IEC 80601-2-30:2009/AMD1:2013

Clinical performance:
- ISO 81060-2:2013
- EN 1060-3:1997+A2:2009

Cuff biocompatibility:
- ISO 10993-5:2009
- ISO 10993-10:2010

Bench tests:
- Internal tests to verify performance
  - Mains and Battery comparison
  - After 500 hour Life Test has been completed
  - After 12 months storage
  - After drop test

The results of the above testing assist in the demonstration of substantial equivalence of the subject device with the predicate device.

Substantial equivalence
The predicate device selected for comparison with the GUS622 Blood Pressure Monitor is:

Predicate Device:	Blood Pressure Monitors Models KD-927 and KD-928
Sponsor:	Andon Health Co., Ltd., China
510(k) Number:	K141984
Clearance Date:	29 April 2015
FDA Product Code:	DXN
Classification Name:	Noninvasive blood pressure measurement system
Regulation No:	21 CFR 870.1130
Class:	II

Predicate device comparison table:
The following Table 1 provides evidence of substantial equivalence of the subject device with the selected predicate device.

Table 1: Predicate device comparison table

Feature	Subject device	Predicate device	Similarity
Device name	GUS622	KD-927/928	N/A
Device Manufacturer	Globalcare, China	Andon Health, China	N/A
510(k) Reference	This submission	K141984	N/A
FDA Product Code	DXN	DXN	Same
FDA Classification Name	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
FDA Regulation Number	21 CFR 870.1130	21 CFR 870.1130	Same
Device description	Automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate via an upper arm cuff.	Automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate via an upper arm cuff..	Same

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Table 1: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Indications for use	The Globalcare GUS622 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.	KD-927 and KD-928 Fully Automatic Electronic Blood Pressure Monitor are for use by medical professionals or at home and are non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22 cm-48 cm.	Substantially equivalent
Use environment	Indoor use, home environment	Indoor use, home and healthcare facilities environments	Difference has no effect on safety or effectiveness
Measuring method	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement	Same
Device measurements (output parameters)	Diastolic and systolic blood pressure Pulse rate	Diastolic and systolic blood pressure Pulse rate	Same
Additional output indications	Irregular heart beat hemodynamic instability	Irregular heart beat hemodynamic instability	Same
Output result calculation	Software algorithm	Software algorithm	Same
Measurement range	Cuff pressure: 0-300 mmHg Systolic: 50-280 mmHg Diastolic: 30-200 mmHg Pulse: 40-199 beats/min	Cuff pressure: 0-300 mmHg Systolic: 60-260 mmHg Diastolic: 40-199 mmHg Pulse: 40-180 beats/minute	Substantially equivalent: Differences have no effect on safety or effectiveness
Accuracy	Pressure: ±3 mmHg Pulse rate: ±5%	Pressure: ±3 mmHg Pulse rate: ±5%	
External Power Supply	Input 100-240Vac 50/60Hz 0.5A max; Output 6VDC (+/-5%) / 600mA (optional)	Input 100-240Vac 50/60Hz 0.5A max; Output 6VDC (+/-5%) / 600 mA	Same
Unit voltage	6V dc	6V dc	Same
Batteries	4 x AAA alkaline 1.5V dc	4 x AAA alkaline 1.5 V dc	Same
Battery life	Approx 500 cycles	Approx 200 cycles	Difference has no effect on safety or effectiveness
Standards compliance	ANSI/AAMI ES60601-1:2005 / A2:2010 IEC 60601-1-11:2015 IEC 60601-1-2:2014 IEC 80601-2-30:2009/ AMD1:2013 ISO 81060-1:2012 EN 1060-3:1997+A2:2009	IEC 60601-1:2005/AC:2010 IEC60601-1-2:2007/AC:2010 IEC 80601-2-30:2009 + Cor.2010	Subject device complies with more recent standards
Device Protection	IEC 60601-1: Class 2	IEC 60601-1: Class 2	Same
Application Part	IEC 60601-1: Type BF	IEC 60601-1: Type BF	Same
Memory	60 x 2 user	60 x 2 user	Same
Dimensions	L 98 mm x W 140 mm x H 53 mm	L 95 mm x W 186 mm x H 56 mm	Differences have no effect on safety or effectiveness
Weight	207 g device without cuff and batteries	330 g without cuff and batteries	Difference has no effect on safety or effectiveness
USB Port?	No	Yes	Different
Compatible PC software?	No	Yes	Different

The subject device and the predicate device have many identical or similar properties or features. The differences that exist and are identified in the above table include:

- Indications for use
- No USB port on subject device
- Subject device has no compatible PC software

None of the identified differences introduce new aspects of safety or effectiveness.

Conclusion
The subject and predicate devices have very similar intended uses and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.